

US EPA ARCHIVE DOCUMENT



NAFTA Technical Working Group on Pesticides  
Grupo de Trabajo Técnico del TLCAN sobre Plaguicidas  
Le groupe de travail technique de l'ALENA sur les pesticides

# **Biopesticides Registration Improvement Course**

## **PRODUCT CHARACTERIZATION AND ANALYSIS 4.1**



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## OVERVIEW

- **US Data Requirements (40 CFR 158.2120)**
  - Online CFR: Electronic Code of Federal Regulations /GPO
  - Guidelines:  
[http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series885.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series885.htm)
- **Presubmission meeting information/feedback**
- **Flexibility in data needs**
  - Current taxonomic data, methods vary
  - Non-guideline data
  - Additional data often needed

## US Data Requirements 40 CFR 158.2120

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes
			MP	EP	
Product Chemistry and Composition					
885.1100	Product Identity	R	MP	EP	--
885.1200	Manufacturing process	R	TGAI and MP	TGAI and EP	--
885.1250	Deposition of a sample in a nationally recognized culture collection	R	TGAI	TGAI	--
885.1300	Discussion of formation of unintentional ingredients	R	TGAI and MP	TGAI and EP	--
Analysis and Certified Limits					
885.1400	Analysis of samples	R	TGAI and MP	TGAI and EP	1
885.1500	Certification of limits	R	MP	EP	--
Physical and Chemical Characteristics					
830.6302	Color	R	TGAI	TGAI	--
830.6303	Physical state	R	TGAI	TGAI	--
830.6304	Odor	R	TGAI	TGAI	--
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	--
830.6317	Storage stability	R	TGAI and MP	TGAI and EP	--
830.6319	Miscibility	R	MP	EP	2
830.6320	Corrosion Characteristics	R	MP	EP	3
830.7000	pH	R	TGAI	TGAI	--
830.7100	Viscosity	R	MP	EP	4
830.7300	Density/relative density/bulk density (specific gravity)	R	TGAI	TGAI	--



## **MICROBIAL PESTICIDE IDENTIFICATION AND PRODUCTION**

- **Taxonomic identification of isolate must be accurate**
  - Extremely important for use of literature or data from a similar strain
  - Best done as an initial company evaluation to see if it is worth continuing product development
    - If close relatives are pathogens, extra testing might be required
- **The potential for contamination must be minimized**
  - OECD (PMRA) is finalizing a new guidance document





## COMMON PROBLEMS / ISSUES

- **Quality control limits for microbial contamination, procedures if limits exceeded**
- **Bioactivity as a QC measure**
- **Deposition of strains (viruses, protists)**
- **CSF - active ingredients, certified limits, related calculations**
- **Strain equivalence**





## COMMON PROBLEMS / ISSUES

- **Known food allergens in formulation**
- **Discussion of toxic metabolites related to AI or near relatives**
- **Host range discussion for broad host range pathogens**
- **Storage stability data and label claims**